Amendments to the Claims

The listing of claims will replace all prior versions, and listings, of claims in the application:

Claim Listing

1. (Currently amended) A vaccine ~~pharmaceutical~~ composition comprising pharmaceutically acceptable particles selected from polymeric microcapsules or liposomes, the particles comprising

~~(i)~~ a biologically active agent that generates a protective immune response in an animal to which it is administered; in combination with

~~(ii) a first~~ an adjuvant chemical which increases the effect of the biologically active agent by acting as an immunostimulant, said adjuvant chemical being selected from the group consisting of ~~one or more of~~:

A) polyornithine,

B) a water soluble vitamin or water soluble vitamin derivative,

C) a positively charged cationic block copolymer or a positively charged cationic surfactant,

D) a clathrate,

E) a complexing agent,

F) cetrimides;

G) an S-layer protein

H) Methyl-glucamine; ~~and~~

~~(iii) a pharmaceutically acceptable carrier or diluent,~~ subject to the following provisos

a) ~~when the chemical (ii) above is selected from D) or L), the protective immune response in an animal to which it is administered;~~

~~b)~~ when the adjuvant chemical ~~(ii) above~~ is selected from A ~~), and the biologically active agent is an agent that generates a protective immune response in an animal to which it is administered~~ , the composition is for administration to a mucosal surface, or

~~c)~~ b) when the adjuvant chemical ~~(ii) above~~ is selected from C ~~) and the biologically active agent is an agent which that generates a protective immune response in an animal to which it is administered~~ , the composition does not contain a polyacrylic acid ~~, and~~

~~d) where the chemical (ii) above is selected from G) and the biologically active agent is an agent that generates a protective immune response in an animal to which it is administered, the carrier or diluent of (iii) is a microsphere or liposome~~ .

2. (Cancelled)

3. (Previously presented) The composition of claim 1 wherein the adjuvant chemical acts as an immunostimulant.

4. (Currently amended) The ~~A~~ composition of claim 1 wherein the ~~said~~ adjuvant chemical is selected from one or more of;

A) ~~the~~ polyornithine ~~has~~ having a molecular weight from 5 to 150kDa;

B) ~~the water soluble vitamin or water soluble vitamin derivative is~~ vitamin E TPGS (d-alpha tocophenyl polyethylene glycol 1000 succinate),

C) ~~the~~ a cationic block copolymer or ~~the~~ a cationic surfactant, ~~is~~ positively charged by means of NH_2^+ groups

D) ~~the~~ a complexing agent that forms complexes with fatty acids, or

E) ~~the clathrate is a~~ cyclodextrin or a derivative thereof.

5. (Cancelled)

6. (Currently amended) The composition of claim ~~5~~ 1 wherein the ~~particle is a microspheres or liposome~~ particles are liposomes.

7. (Currently amended) The composition of claim ~~6~~ 1 ~~which comprises a microsphere~~ wherein the particles are microcapsules.

8. (Currently amended) The composition of claim 7 wherein the ~~microsphere is~~ microspheres are prepared using a high molecular weight polymer.

9. (Previously presented) The composition according to claim 8 wherein the polymer has a molecular weight of 100kDa or more.

10. (Previously presented) The composition according to any one of claims 7 to 9 wherein the microsphere comprises poly-(L-lactide).

11. (Cancelled)

12. (Previously presented) The composition of claim 1 which is administered to a mucosal surface of an animal or administered parenterally to the animal.

13. (Previously presented) The composition of claim 2 which further comprises a second adjuvant.

14. (Withdrawn) A method of producing a prophylactic or therapeutic vaccine, which method comprises encapsulating a polypeptide which is capable of producing a protective immune response in a first polymeric material which has a high molecular weight, in the presence of a second polymeric material which increases the biological effect of the composition.

15. (Withdrawn) A method of protecting a mammal against infection, which method comprises administration of a composition according to claim 1 to a mammal.

16. (Withdrawn) A method according to claim 15 wherein the composition is applied to a mucosal surface.

17. (Withdrawn) A method according to claim 16 wherein the mucosal surface comprises an intranasal surface.

18. (Withdrawn) A microsphere comprising a polymeric carrier and an S-layer protein.

19. (Withdrawn) A microsphere according to claim 18 wherein said S-layer protein is coated on the surface of the microsphere.

20. (Withdrawn) A microsphere according to claim 18 which further comprises an agent that is capable of generating a protective immune response in an animal to which it is administered.

21. (Withdrawn) A microsphere according to claim 20 wherein one or more of said agents are linked to the S-layer protein.

22. (Withdrawn) A pharmaceutical composition comprising a microsphere according to claim 19.

23. (Withdrawn) A pharmaceutical composition according to claim 22 wherein said composition is a vaccine, intended to produce a protective immune response against a bacterium, and said S-layer protein is derived from said bacterium.

24. (Withdrawn) The use of a chemical selected from

A) a polyamino acid,

B) a water soluble vitamin or vitamin derivative,

C) positively charged cationic pluronics,

D) a clathrate,

E) a complexing agent,

F) cetrimides,

G) an S-layer protein, or

H) Methyl-glucamine

as an immunostimulant, provided that in the case of A), the immunostimulant is applied to a mucosal surface, in the case of C, the compound is used in the absence of a polyacrylic acid.

25. (Withdrawn) The use of an adjuvant chemical selected from

A) a polyamino acid,

B) a water soluble vitamin or vitamin derivative,

C) positively charged cationic pluronics,

D) a clathrate,

E) a complexing agent,

F) cetrimides,

G) an S-layer protein, or

H) Methyl-glucamine

as an immunostimulant in the production of a vaccine for use in prophylactic or therapeutic treatment, provided that in the case of A), the immunostimulant is used in a vaccine which is

applied to a mucosal surface, in the case of C), the compound is used in the absence of a polyacrylic acid.

26. (Currently amended) The composition of claim ~~4~~ 30 wherein

~~A)~~ the complexing agent forms complexes with deoxycholic acid ~~; or~~

~~B) the clathrate is dimethyl-β-cyclodextrin~~ .

27. (New) The composition of claim 1 wherein the adjuvant chemical is polyornithine having a molecular weight from 5 to 150 kDa.

28. (New) The composition of claim 1 wherein the adjuvant chemical is a water soluble vitamin or water soluble vitamin derivative comprising vitamin E TPGS (d-alpha tocophenyl polyethylene glycol 1000 succinate).

29. (New) The composition of claim 1 wherein the adjuvant chemical is a cationic block copolymer or a cationic surfactant, positively charged by means of NH_2^+ groups.

30. (New) The composition of claim 1 wherein the adjuvant chemical is a complexing agent that forms complexes with fatty acids.

31. (New) The composition of claim 1 wherein the adjuvant chemical is a clathrate comprising cyclodextrin or a derivative thereof.

32. (New) The composition of claim 31 wherein the clathrate is dimethyl-ß-cyclodextrin.